§170.315(g)(6) Consolidated CDA creation performance

2015 Edition Cures Update CCG

Version 1.0 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	06-15-2020

Regulation Text

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§170.315 (g)(6) *Consolidated CDA creation performance—*

The following technical and performance outcomes must be demonstrate
Consolidated CDA creation. The capabilities required under paragraphs (g
section can be demonstrated in tandem and do not need to be individually
or sequentially.

(i) This certification criterion's scope includes:

(A) The data classes expressed in the standard in § 170.213, and in a
170.205(a)(4) and (5), and the paragraphs (g)(6)(i)(*C*)(*1*)-(*3*) of this se

(B) The Common Clinical Data Set in accordance with § 170.205(a)(
(6)(i)(*C*)(*1*) through (*4*) of this section for the period until May 2, 2022.

(C) The following data classes:

(1) Assessment and plan of treatment. In accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or in accordance with the "Assessment Section (V2)" and "Plan of Treatment Section (V2)" of the standard specified in § 170.205(a)(4).

(2) Goals. In accordance with the "Goals Section" of the standard specified in § 170.205(a)(4).

(3) Health concerns. In accordance with the "Health Concerns Section" of the standard specified in § 170.205(a)(4).

(4) Unique device identifier(s) for a patient's implantable device(s). In accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the standard specified in § 170.205(a)(4)

(ii) *Reference C-CDA match.*

(A) For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that matches a gold-standard, reference data file.

(B) For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.

(iii) *Document-template conformance.*

(A) For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.

(B) For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demo
implementation of each document template applicable to the certi
criteria within the scope of the certificate sought.

(iv) *Vocabulary conformance.*

(A) For a health IT certified to (g)(6)(i)(A) of this section, create a dat
accordance with the standard adopted in § 170.205(a)(4) and (5) tha
required vocabulary standards (and value sets) are properly implem

(B) For health IT certified to (g)(6)(i)(B*)* of this section, create a data
accordance with the standard adopted in § 170.205(a)(4) that demonstrates the vocabulary standards (and value sets) are properly implemented.

(v) *Completeness verification*. Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in either (g)(6)(i)(A) or (B) of this section, as applicable.

Standard(s) Referenced

Applies to entire criterion

§ 170.213 United States Core Data for Interoperability (USCDI)

§ 170.205(a)(4) HL7 Implementation Guide (IG) for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata).

§ 170.205(a)(5) Health Level 7 (HL7®) CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5).

Certification Companion Guide: Consolidated CDA creation performance

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the *21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification Program* Final Rule (ONC Cures Act Final Rule.) It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the ONC Cures Act Final Rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition
New	No	Not Included

Certification Requirements

This certification criterion was adopted at § 170.315(g)(6), and is required f certification to 2015 Edition certification criteria with Consolidated-Clinical Document Architecture (C-CDA) creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(4), (b)(6), (b)(9), (e)(1), and (g)(9)). There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The specific requirements in provisions (g)(6)(i)-(iv) can be demonstrated in tandem.
- This certification criterion focuses on the data expressed in the USCDI.

- If the scope of the certification includes more than one certification criterion with C-CDA creation required, C-CDA creation performance only has to be demonstrated once for each C-CDA document template (e.g., C-CDA creation performance to the Continuity of Care Document (CCD) template would not have to be demonstrated twice if the Health IT Module presents for certification to both the transitions of care and data export criteria). [see also 80 FR 62674]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 IG for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see Frequently Asked Questions #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA doc
day delay from the time the CCG has been updated with the ONC-appro
when compliance with the corrections will be required to pass testing (
Validator). Similarly, there will be an 18-month delay before a finding of
in certified health IT during surveillance would constitute a non-confor
Program.
- C-CDA files created during testing (using test data) will be retained by N
Testing Labs and contributed to an ONC-maintained repository. [see al

Paragraph (g)(6)(i)

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7 C-CDA Release 2.1 IG that matches a gold-standard, reference data file.

Clarifications:

- Sample gold standard C-CDA documents are available on an ONC-maintained repository. [see also 80 FR 62675]
- On the gold standard match, the exact match is expected for the coded test data provided to the system under test for creation. In other words, the developer-submitted C-CDA will be

matched with a gold standard C-CDA for the test data that is provided to the developer.

Paragraph (g)(6)(ii)

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7 C-CDA Release 2.1 IG for each document template applicable to the certification criteria within the scope of the certification.

Clarifications:

- No additional clarifications available.

Paragraph (g)(6)(iii)

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7 C-CDA Release 2.1 IG that shows the required vocabulary standards and that value sets are properly implemented.

Clarifications:

- No additional clarifications available.

Paragraph (g)(6)(iv)

Technical outcome – The health IT can create a C-CDA file in accordance w
Release 2.1 IG that includes at a minimum all of the data classes in the USC

Clarifications:

- This provision intends to ensure that the data entered into the health IT system (via whatever workflow and functionality) can be reflected in a C-CDA file created by the system and not be missing data a user otherwise recorded. [see also 80 FR 62675]

Content last reviewed on June 22, 2020